

Exhibit 3

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Safety
Enforcement Report for March 2, 2005

The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

March 2, 2005
05-09

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I
PRODUCT

ACME Sliced Smoked Nova Salmon, NET WT. 8 OZ. (227 g). --- INGREDIENTS: SMOKED SALMON (SALMON, SALT, SUGAR, NATURAL HARDWOODSMOKE, SODIUM NITRITE). The product is packaged in a plastic tub container with a plastic lid. Barcode # 0 23384 10105 7. Recall # F-193-5.

CODE

SELL BY 122404.

RECALLING FIRM/MANUFACTURER

Acme Smoked Fish Corp, Brooklyn, NY, by press release and letter, dated 12/30/04. Firm initiated recall is complete.

REASON

The product was found to be contaminated with *Listeria monocytogenes*, a pathogenic organism, based on sampling & analysis by the New York State Department of Agriculture & Markets.

VOLUME OF PRODUCT IN COMMERCE

204 , 8 oz. units.

DISTRIBUTION

NY.

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II
PRODUCT

Ultra Flu and Ultra Cap, Nasal Decongestant, Cough Suppressant, Antihistamine, (500 mg acetaminophen, 15 mg dextromethorphan HBr, 2 mg chlorpheniramine maleate) Pain Reliever, Fever Reducer, 25 tablets per bottle, NDC #11383-227-25 and NDC #11383-226-25. Recall # D-133-5.

CODE

Lot #4293, Exp. 9/05.

RECALLING FIRM/MANUFACTURER

Weeks & Leo, Co., Inc., Urbandale, IA, by letter dated December 31, 2004 and by letter and telephone on January 14, 2005. Firm initiated recall is ongoing.

REASON

Labeling: Label lacks the declaration of pseudoephedrine HCl 30 mg.

VOLUME OF PRODUCT IN COMMERCE

2,342/25-tablet bottles.

DISTRIBUTION

Nationwide.

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS III
PRODUCT

a) Pramoxine cream 1% (hydrocortisone acetate 1% and pramoxine HCl 1%) packaged in 3 gram professional sample size metal tubes; Rx only, NDC 0496-0716-33. Recall # D-134-5;

b) Pramoxine cream, 2.5% (hydrocortisone acetate 2.5% and pramoxine HCl 1%), packaged in 3 gram professional sample size metal tubes; Rx only, NDC 0496-0717-33. Recall # D-135-5.

CODE

a) Lot 03083B, Exp. 04/05;

b) Lot 030909A, Exp. 04/05;

Lot 03229A, Exp. 10/05 and

Lot 04047A, Exp. 03/06.

RECALLING FIRM/MANUFACTURER

Ferndale Laboratories, Inc., Ferndale, MI, by letters mailed between February 4, 2005 and February 8, 2005. Firm initiated recall is ongoing.

REASON

Defective container: The metal tubes may have pinhole defects, which would result in a super potent product.

VOLUME OF PRODUCT IN COMMERCE

561,260 tubes.

DISTRIBUTION

Nationwide.

PRODUCT

a) Imodium Advanced Caplets (Loperamide HCl 2 mg

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Unit numbers: 18FQ91014, 18FQ91018, 18FQ91019, 18FQ91020, 18FQ91021, 18FQ91022, 18FQ91023, 18FQ91024, 18FQ91027, 18FQ91028, 18FQ91029, 18FQ91030, 18FQ91031, 18FQ91032, 18FQ91033, 18FQ91034, 18FQ91035, 18FQ91036, 18GQ91037, 18FQ91038, 18FQ91039, 18FQ91040, 18FQ91042, 18FQ91043, 18FQ91044, 18FQ91046, 18FQ91048, 18GF47000, 18GF47001, 18GF47004, 18GF47005, 18GF47006, 18GF47008, 18GF47010, 18GN26801, 18GN26802, 18GN26804, 18GN26807, 18GN26808, 18GN26810, 18GN26812, 18GN26813, 18GN26815, 18GN26816, 18GN26817, 18GN26818, 18GN26819, 18GN26820, 18GN26821, 18GN26822, 18GN26825, 18GN26827, 18GN26828, 18GN26829, 18GN26830, 18GN26831, 18GN26832, 18GN26833, 18GN26834 and 18GN26835.

RECALLING FIRM/MANUFACTURER

American Red Cross, Great Lakes Region, Lansing, MI, by telephone on December 31, 2003, by facsimile on January 2, 2004, and by letter, dated January 7, 2004. Firm initiated recall is complete.

REASON

Blood products, collected without daily quality control being performed, were distributed.

VOLUME OF PRODUCT IN COMMERCE

60 Units.

DISTRIBUTION

MI and PA.

PRODUCT

Red Blood Cells, Leukocytes Reduced. Recall # B-0690-5.

CODE

Unit number 40LV05536.

RECALLING FIRM/MANUFACTURER

The American National Red Cross, Heart of America Region, Peoria, IL, by telephone on November 29, 2004, and by letter on December 7, 2004. Firm initiated recall is complete.

REASON

Blood product, that did not have the complete amount of additive solution included, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit.

DISTRIBUTION

IL.

PRODUCT

Source Plasma. Recall # B-0699-5.

CODE

Unit 77428554.

RECALLING FIRM/MANUFACTURER

Bio-Blood Components, Inc., Hammond, IN, by facsimile on November 19, 2004. Firm initiated recall is complete.

REASON

Blood product, collected from a donor whose eligibility to donate was not adequately verified, was distributed.

VOLUME OF PRODUCT IN COMMERCE

1 unit.

DISTRIBUTION

CA.

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II**PRODUCT**

Trinica Bone Tap Instrument, Catalog Number 07.00168.001, sold separately and as part of Zimmer Spine Trinica Anterior Cervical Plating Instrument sets (catalog numbers 07.00215.001 and 07.00546.001). Only the Trinica Bone Tap Instruments are being recalled from the sets. Recall # Z-1014-04.

CODE

Lot P020077.

RECALLING FIRM/MANUFACTURER

Zimmer Spine, Inc., Minneapolis, MN, by letters dated May 25, 2004. Firm initiated recall is ongoing.

REASON

The recalled bone taps could break inside the vertebral body during the tapping process.

VOLUME OF PRODUCT IN COMMERCE

51 units.

DISTRIBUTION

HI, NY, SC, and SD.

PRODUCT

Nichols Advantage 25-Hydroxy Vitamin D Assay, Catalog number 62-7033. Recall # Z-1118-04.

CODE

Not limited to specific lots.

RECALLING FIRM/MANUFACTURER

Nichols Institute Diagnostics, San Clemente, CA, by Customer Bulletin on June 30, 2004. Firm initiated recall is ongoing.

REASON

Lower than expected results are obtained.

VOLUME OF PRODUCT IN COMMERCE

Not specified.

DISTRIBUTION

Nationwide, and Internationally.

PRODUCT

The device generates whole body and head multislice X-ray computed tomography images that are used by the physician in the diagnosis of disease. Brand Name: CT/e; CT/e Dual; CT/e Plus; CT/e Dual Plus; CT/e Lite; ProSpeed AI; ProSpeed AIi; ProSpeed FII; ProSpeed EII; CT HiSpeed Series. Recall # Z-0269-05.

CODE

Model or Catalog: 2297024, 2320315, 2244226, 2113694-2, 2115992-4, 2200290-2.

RECALLING FIRM/MANUFACTURER

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Safety
Enforcement Report for May 18, 2005

The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

May 18, 2005
05-20

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I
PRODUCT

Golden Lion® Dried Ziziphus Jujuba Mill, net wt. 12 oz. (340g). Product is a dried Chinese red dates packed in a sealed flexible plastic bag. Recall # F-280-5.

CODE

Barcode # 7 34765 04061 1.

RECALLING FIRM/MANUFACTURER

Recalling Firm: Blooming Import Inc., Brooklyn, NY, by press release on October 8, 2004. Manufacturer: Daxin Huafeng Food Co. Ltd., Taishan, China. Firm initiated recall is complete.

REASON

Sampling and analysis by the New York State Department of Agriculture & Markets revealed that the product contained undeclared sulfites (290 ppm).

VOLUME OF PRODUCT IN COMMERCE

72 cases (50 -- 12 oz. packages per case).

DISTRIBUTION

NY, NJ, GA, NC, MD and D.C.

PRODUCT

a) Ziyad Brand Imported Tahini; sesame seed paste packaged in 16 oz., UPC 74265-00156; 32 oz. UPC 74265-00155 (12 jars per case); 64 oz. glass jars, (6 jars per case), UPC 74265-00307; and 128 oz. (4 jars per case) plastic jars, UPC 74265-00093. Recall # F-281-5;
b) Ghandour Tahina 100% Crushed Sesame Seeds; sesame paste packaged in 640 oz. (40 lb.) white plastic pails with green lids and a wire handle; Product of Lebanon. No UPC codes on the containers. Recall # F-282-5.

CODE

There are no lot numbers on the containers. All sizes of all products labeled as Ziyad Brand Imported Tahini are under recall.

RECALLING FIRM/MANUFACTURER

Syrian Bakery Company, Inc., D.B.A., Ziyad Brothers Importing, Cicero, IL, by press release dated April 11, 2005. Firm initiated recall is ongoing.

REASON

Tahini was found contaminated with Salmonella by the Minnesota Dept. of Agriculture, the Illinois Dept. of Public Health, and the FDA.

VOLUME OF PRODUCT IN COMMERCE

35,868 jars and 237 pails.

DISTRIBUTION

Nationwide.

PRODUCT

a) Smoked Atlantic Salmon in 4 oz, 8 oz, 12 oz, 16 oz and larger packages. All flavored varieties listed below were manufactured from the same lot of salmon and various expiration dates.
Recall # F-284-5;
b) Moroccan Salmon, one of the flavored varieties.
Recall # F-285-5;
c) Smoked Salmon Scampi, one of the flavored varieties. Recall # F-286-5;
d) Salmon Bacon, one of the flavored varieties.
Recall # F-287-5;
e) Ming Tsai's 5-Spice Chile Tea Rub Smoked Salmon, one of the flavored varieties. Recall # F-288-5;
f) Salmon Gravelox, one of the flavored varieties.
Recall # F-289-5;
g) Czar Cut Salmon Tenderloin. Recall # F-290-5;
h) Pastrami Salmon, one of the flavored varieties.
Recall # F-291-5.

CODE

a)- h) Lot 4328 of bulk salmon manufactured into various flavors labeled as Lot 4328 and various expiration dates listed below: 1/29/05; 1/30/05; 1/31/05; 2/01/05; 2/02/05; 2/03/05;

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8363R with lot no.'s 11232452, 11209241, 11170011, 11134085, 11044590, 11280218, 11355877A, 11319313, 11362213, 11335475, 11322560, 11277524 and 11221479; Total System TS8275R2 with Lot No.'s 11143684, 11117484, 11113585 and 11078654; Total System TS8287R with Lot no. 11304060; Total System TS8299R with Lot no.'s 11237797 and 11207329; Total System TS8385R with lot no.'s 10890724 and 11157079A; Total System TS8329R3 With Lot no.'s 11319074, 11282455, 11269241, 11260213, 11237174, 11211041, 11355036 and 11326059; Total System TS8339R1 with Lot no.'s 11240930, 1161677 and 11364737; Total System TS8394R1 with Lot no. 11275457; Total System TS8329R3 with Lot no.'s 11454233, 11435228, 11404947 and 11392251; Total System TS8390R with Lot no. 11019052; and Total System TS 8367R1 with Lot no.'s 11247834, 11107184, 11063353, 11033869, 11355872, 11278049 and 11144479.

RECALLING FIRM/MANUFACTURER

Recalling Firm: Medtronic Perfusion Systems, Brooklyn Park, MN, by letters beginning March 25, 2005.

Manufacturer: Medtronic Mexico, S. De R.L. De C.V., Tijuana, Baja California, Mexico. Firm initiated recall is ongoing.

REASON

Some warehouse inventory of Custom Pack product bags were found with ruptured seals. The seals were partially opened in the center of the bag's Tyvek edge. Since this bag is used to enclose and seal the custom pack assembly and had been sterilized, the ruptured seal breaches the sterility barrier for the package.

VOLUME OF PRODUCT IN COMMERCE

4,131 devices (3,373 within US).

DISTRIBUTION

Nationwide and Internationally.

PRODUCT

Nichols IRMA Intact PTH Assay, catalog No. 40-2171. Recall # Z-0809-05.

CODE

Lots 40-504553/4 released March 4, 2005 and kit lots 40-501687/8 released March 18, 2005.

RECALLING FIRM/MANUFACTURER

Nichols Institute Diagnostics, San Clemente, CA, by letters on March 9 and 11, 2005. Firm initiated recall is ongoing.

REASON

Firm noted a change in performance and therefore changed the labeled performance specifications in the Directional Insert portion of the labeling.

VOLUME OF PRODUCT IN COMMERCE

Not divulged.

DISTRIBUTION

Nationwide and Internationally.

PRODUCT

Bio-Intact PTH (1-84) Assay, Catalog No. 62-7040. Recall # Z-0810-05.

CODE

Lots 62-402598 and 62-402622.

RECALLING FIRM

Nichols Institute Diagnostics, San Clemente, CA, by letters dated March 25, 2005. Firm initiated recall is ongoing.

REASON

Values do not agree with Directional Instructions (DI). Lot 62-402598's results were outside the DI claim for functional sensitivity, reproducibility, parallelism and two interfering substances. Lot 62-402622's results were outside the DI claim for functional sensitivity, reproducibility, recovery, parallelism and two interfering substances.

VOLUME OF PRODUCT IN COMMERCE

13,751.

DISTRIBUTION

Nationwide and Internationally.

PRODUCT

The Heartport EndoClamp aortic catheter is a 10.5 Fr. wirewound, three-lumen catheter with an elastomeric balloon near its tip. This device is used with a 200 cm j-hook guide wire accessory device. Product Code EC1001. Recall # Z-0811-05.

CODE

Lot Number, exp. date: MS020434, EXP APRIL-2005; MS0504003, EXP APRIL-2005; MS0504027, EXP MAY-2005; MS0604006, EXP MAY-2005; MS0604007, EXP MAY-2005; MS0704006, EXP JUNE-2005; MS0704015, EXP JUNE-2005; MS0804007, EXP AUGUST-2005; MS1004007, EXP OCTOBER-2005; MS1104021, EXP OCTOBER-2005; MS0105002, EXP JANUARY-2006; MS0105047, EXP FEBRUARY-2006; MS0205039, EXP FEBRUARY-2006; MS0205036, EXP MARCH-2006; MS0205041, EXP MARCH-2006; MS0205042, EXP MARCH-2006.

RECALLING FIRM/MANUFACTURER

Recalling Firm: Heartport, Inc., Somerville, NJ, by telephone on April 8, 2005.

Manufacturer: MedSource Technologies-LaConia, LaConia, NH. Firm initiated recall is ongoing.

REASON

Guidewire is protruding through the film portion of the packages which compromises the sterility of the device.

VOLUME OF PRODUCT IN COMMERCE

1,029 units.

DISTRIBUTION

Nationwide and Internationally.

PRODUCT

a) ENTrak Navigation and Visualization System.

Recall # Z-0812-05;

b) ENTrak Plus Navigation and Visualization System.

Recall # Z-0813-05;

c) InstaTrak 3500 Navigation and Visualization System.

Recall # Z-0814-05;

d) InstaTrak 3500 Plus Navigation and Visualization System.

Recall # Z-0815-05;

CODE

Axcess System Kit P/N: 1005869-001.

RECALLING FIRM/MANUFACTURER

GE OEC Medical Systems, Inc., Salt Lake City, UT, by letter on July 12, 2004. Firm initiated recall is ongoing.

REASON

Navigation inaccuracy may result if the headset registration method is used with the Axcess System Kit.

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Enforcement Report for August 3, 2005

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August 3, 2005
05-31

RECALLS AND FIELD CORRECTIONS: FOODS AND COSMETICS -- CLASS

PRODUCT

Nabisco 100 Calorie Packs Oreo Thin Crisps Baked Chocolate Wafer Snacks, 4.86 oz. cartons containing six individual serving bags, 6 cartons per case, UPC 446170, Recall # F-544-5

CODE

Best When Used By 04DEC05BD case code 5338BD

RECALLING FIRM/MANUFACTURER

Recalling Firm: Kraft Inc., Northfield, IL, by press release on July 11, 2005.

Manufacturer: Consolidated Biscuit Company, Mc Comb, OH. Firm initiated recall is ongoing.

REASON

Some of the boxes of Nabisco 100 Calorie Packs Oreo Thin Crisps may contain some individual bags of Nabisco 100 Calorie Packs Chips Ahoy Thin Crisps which are made with milk, not declared on the Oreo box.

VOLUME OF PRODUCT IN COMMERCE

17,102 cases

DISTRIBUTION

Nationwide

PRODUCT

- a) Beef and Cheese sub sandwich, net wt. 8 oz., EASTSIDE DELI brand, Recall # F-547-5;
- b) Beef and Cheese sandwich on wheat bread, net wt. 6 oz., FRESH FROM THE DELI brand, Recall # F-548-5;
- c) Ham and cheese submarine sandwich, net wt. 8 oz., EASTSIDE DELI brand, Recall # F-549-5;
- d) Ham and swiss on onion sub bun, net wt. 8 oz., EASTSIDE DELI brand, Recall # F-550-5;
- e) Ham and cheese sandwich on wheat bread, net wt. 5.5 oz., EASTSIDE DELI brand, Recall # F-551-5;
- f) Ham and cheese sandwich on white bread, net wt. 6 oz. or 229 grams, FRESH FROM THE DELI brand, Recall # F-552-5;
- g) Ham and cheese sandwich on white sub bun, net wt. 4 oz., In Your Belly Deli brand, Recall # F-553-5;
- h) Ham and cheese buddy sandwich on white bun, net wt. 6.5 and 8 oz., EASTSIDE DELI brand, and Fresh from the Deli brand, Recall # F-554-5;
- i) Charbroil beef patty sandwich on white bun, net wt. 4.75 oz., In Your Belly Deli brand, Recall # F-555-5;
- j) Super beef patty sandwich on white seeded bun, net wt. 5.5 oz., EASTSIDE DELI brand, In Your Belly Deli and FRESH FROM THE DELI brand labels. Recall # F-556-5;
- k) Super beef patty on white bun sandwich, net wt. 7 oz., FRESH FROM THE DELI brand, Recall # F-557-5;
- l) Gigantic cheeseburger on white seeded bun, 100% ground beef, net wt. 6.5 oz., EASTSIDE DELI brand, Recall # F-558-5;
- m) Gigantic beef burger on white seeded bun, 100% pure beef, net wt. 7.5 oz., Fresh from the Deli brand, Recall # F-559-5;
- n) 'MEGA' Bacon cheeseburger sandwich on white seeded bun, net wt. 8.5 oz., EASTSIDE DELI brand, Recall # F-560-5;
- o) Bacon & Beef Patty sandwich on white seeded bun, Net wt. 7 oz., FRESH FROM THE DELI brand, Recall # F-561-5;

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972, 1170, 1171, 1172, 1270 and 1272) pacemaker,
Recall # Z-1034-05;
d) PULSAR MAX II (model nos. 1180, 1181 and 1280)
pacemaker, Recall # Z-1035-05;
e) DISCOVERY II (model nos. 481, 981 1184, 1186, 1187,
1283, 1284, 1285 and 1286) pacemaker,
Recall # Z-1036-05;
f) VIRTUS PLUS II (model nos. 1380 and 1480) pacemaker,
Recall # Z-1037-05;
g) INTELES II (model nos. 1349, 1384, 1385, 1483,
1484, 1485 and 1499) pacemaker, Recall # Z-1038-05;
h) CONTAK TR (model no. 1241) pacemaker,
Recall # Z-1039-05

CODE

a) Model 1174: Serial numbers 109017 thru 115660,
Model 1175: Serial numbers 200731 thru 202199,
Model 1273: Serial numbers 315516 thru 324528,
Model 1274: Serial numbers 296080 thru 496546,
Model 1275: Serial numbers 500705 thru 501661;
b) Model 476: Serial numbers 103316 thru 106064,
Model 976: Serial numbers 202612 thru 205357,
Model 1176: Serial numbers 303330 thru 306689,
and Model 1276: Serial numbers 404640 thru 409060;
c) Model 470: Serial numbers 101150 thru 101894,
Model 870: Serial numbers 200201 thru 201205,
Model 970: Serial numbers 300808 thru 301676,
Model 972: Serial numbers 452959 thru 454562,
Model 1170: Serial numbers 100610 thru 103665,
Model 1171: Serial numbers 300733 thru 302575,
Model 1172: Serial numbers 594273 thru 594437,
Model 1270: Serial numbers 595951 thru 608303,
Model 1272: Serial numbers 600250 thru 600749;
d) Model 1180: Serial numbers 100001 thru 100055,
Model 1181: Serial numbers 300001 thru 300050,
Model 1280: Serial numbers 500003 thru 500525;
e) Model 481: Serial numbers 100000 thru 100115,
Model 981: Serial numbers 200002 thru 200041,
Model 1184: Serial numbers 300012 thru 300061,
Model 1186: Serial numbers 500000 thru 500054,
Model 1187: Serial numbers 450000 thru 450010,
Model 1283: Serial numbers 600001 thru 600073,
Model 1284: Serial numbers 700000 thru 700079,
Model 1286: Serial numbers 900000 thru 900059;
f) Model 1380: Serial numbers 100000 thru 100044,
Model 1480: Serial numbers 500005 thru 500072;
g) Model 1349: Serial numbers 100003 thru 100076,
Model 1384: Serial numbers 300000 thru 300073,
Model 1385: Serial numbers 400005 thru 400019,
Model 1483: Serial numbers 600005 thru 600082,
Model 1484: Serial numbers 700005 thru 700064,
Model 1485: Serial numbers 800005 thru 800053,
Model 1499: Serial numbers 200001 thru 200073;
h) Serial numbers 200128 thru 200479

RECALLING FIRM/MANUFACTURER

Recalling Firm: Guidant Corp-Cpi Division, Saint Paul, MN, by letter dated July 18, 2005.
Manufacturer: Guidant-Ireland, Clonmel, Ireland. Firm initiated recall is ongoing.

REASON

A hermetic sealing component utilized in the device may experience a gradual degradation, resulting in a higher than normal moisture content within the pacemaker case late in the device's service life.

VOLUME OF PRODUCT IN COMMERCE

34,026

DISTRIBUTION

Nationwide and Internationally

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II**PRODUCT**

Nichols Advantage ACTH Test System, catalog number 62-7004, Recall # Z-1044-05

CODE

Lot numbers: 62-500040 and 62-404296

RECALLING FIRM/MANUFACTURER

Nichols Institute Diagnostics, San Clemente, CA, by letters on April 22 and 29th, 2005. Firm initiated recall is ongoing.

REASON

Performance does not meet claims in the Directional Insert concerning correlation with the IRMA ACTH assay.

VOLUME OF PRODUCT IN COMMERCE

1,599

DISTRIBUTION

Nationwide and Internationally

PRODUCT

Ohmeda Medical's Giraffes OmniBeds and Giraffe Incubators, Recall # Z-1047-05